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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,424	11/03/2003	David W. Johnson	CALW-004/01US 306562-2009	1511
58249 7590 03/31/2008 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001			EXAMINER ROBINSON, KEITH O NEAL	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 03/31/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/698,424	Applicant(s) JOHNSON ET AL.	
	Examiner KEITH O. ROBINSON	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 6-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 6-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/12/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicant's cancellation of claims 1, 5 and 20-29, filed December 12, 2007, have been received and entered in full.

Claims 2-4 and 6-19 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112, first paragraph – Written Description

Claims 2-4 and 6-19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office Action mailed June 12, 2007 (see pages 2-4). Applicant's arguments, filed December 12, 2007, have been fully considered but are not persuasive.

Applicant requests that the Examiner provides the statute, rule and/or case law that supports the preposterous contention that Applicant is somehow required to demonstrate that they were in possession of "each and every alfalfa plant with the claimed characteristics" at the time of filing (see page 7, 3rd paragraph of 'Remarks' filed December 12, 2007).

See MPEP 2163(I) where it states “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116”.

Applicant appears to claim any alfalfa plant having the claimed characteristics, even those that are made by other methods than those described in the specification. However, the specification only provides evidence that Applicant was in possession of alfalfa variety CW 75046 (see pages 25-29), CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45) and describes specific methods for producing said varieties. Therefore, it is unclear how Applicant can be in possession of alfalfa plants having the same characteristics but produced by different methods or produced using different parental materials.

Applicant argues that they are not claiming just any *Medicago sativa* alfalfa plant with faster recovery and more erect stems, but rather are claiming *Medicago sativa* alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest coupled with having 15% or greater more erect stems at late bloom when compared to specific commercial check varieties, wherein such checks were the best commercial check varieties available at the time of the present invention and are thus, not claiming just any *Medicago sativa* alfalfa plant, but rather are claiming just any *Medicago sativa* alfalfa varieties with specific and clearly defined traits hitherto unknown to those skilled

in the art of alfalfa breeding (see page 7, last paragraph to page 8, 1st paragraph of 'Remarks' filed December 12, 2007).

This is not persuasive. See MPEP 2163(I) where it states “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116”.

The specification only provides evidence that Applicant was in possession of alfalfa variety CW 75046 (see pages 25-29), CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45) and does not provide evidence of possession of every alfalfa plant with the claimed characteristics as is broadly claimed. Of the above mentioned varieties, only CW 75046, CW 83201, and CW 95026 are disclosed as having improved standability (i.e. more erect stems) and fast recovery after spring green-up or after harvest (see above cited pages). Alfalfa variety CW 85029 does not appear to have the claimed traits.

Also see MPEP 2163.02 where it states, “[a]n objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)”.

In the instant invention, one of ordinary skill in the art would only recognize that Applicant has invented has only invented alfalfa varieties CW 75046 (see pages 25-29),

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CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45).

In the instant case, Applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicant was in possession of alfalfa varieties CW 75046 (see pages 25-29), CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45) and not each and every alfalfa plant with the claimed characteristics as is broadly claimed.

Thus, based on the disclosure of the specification, Applicant has only shown possession of alfalfa varieties CW 75046, CW 83201, CW 85029 and CW 95026.

Applicant argues that the as-filed specification provides detailed descriptions of the development of four very different and distinct *Medicago sativa* alfalfa varieties derived from diverse genetic backgrounds, wherein each of these varieties clearly meet the limitations of the claims (see page 8, 2nd paragraph of 'Remarks' filed December 12, 2007).

This is not persuasive. The Examiner agrees that the specification provides detailed descriptions of the development of four very different and distinct *Medicago sativa* alfalfa varieties derived from diverse genetic backgrounds, namely alfalfa varieties CW 75046 (see pages 25-29), CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45); however, the claims are broadly drawn to any alfalfa plant having the claimed characteristics, even those that are made by other methods, or produced using different parental materials, than those described in the specification.

Applicant argues that anyone skilled in the art can follow the procedures described in the specification to develop additional varieties which have the claimed characteristics (see page 8, 2nd paragraph to page 9, lines 1-13 of 'Remarks' filed December 12, 2007).

This is not persuasive. One skilled in the art could not follow the procedures described in the specification to develop additional varieties which have the claimed characteristics because the procedures described in the specification use uncharacterized parental materials. See, for example, page 25, lines 6-7 of the specification where it states "CW 75046' is a synthetic variety with 225 parent plants that were selected for resistance to Phytophthora root rot". However, the specification does not describe any of the 225 parent plants nor is there any description of the breeding methods used with, for example, the 225 parent plants to produce alfalfa variety 'CW 75046'.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

Claims 2-4 and 6-19 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alfalfa varieties CW 75046, CW 83201, CW 85029 and CW 95026, does not reasonably provide enablement for any and all alfalfa plants having the same characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office Action mailed June 12, 2007

(see pages 4-7). Applicant's arguments, filed December 12, 2007, have been fully considered but are not persuasive.

Applicant argues the Examiner must consider all of the evidence related to each of the eight considerations in *In re Wands* and that the Examiner seems to pick and choose a different subset of the Wands factors with each Office Action (see page 9, last two lines to page 10, lines 1-11 of 'Remarks' filed December 12, 2007).

This is not persuasive. There is no requirement for the Examiner to address each of the eight considerations in *In re Wands*. The Examiner has addressed those considerations that are of issue for this case. With regard to the Examiner "picking and choosing a different subset of the Wands factors with each Office Action", each Office Action is examined on its own merits.

Applicant argues that the Examiner's extremely broad-stroked rejection is not the standard set by Congress, the courts or the U.S. Patent and Trademark Office and that the Examiner has committed a clear error with regard to the breadth of the claims under the enablement rejection (see page 10, 2nd paragraph of 'Remarks' filed December 12, 2007).

This is not persuasive. See MPEP 2164.08 where it states, "[t]he breadth of the claims was a factor considered in *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991). In the *Amgen* case, the patent claims were directed to a purified DNA sequence encoding polypeptides which are analogs of erythropoietin (EPO). The Court stated that: *Amgen* has not enabled preparation of DNA sequences sufficient to support its all-encompassing claims. . . .

[D]espite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. . . This disclosure might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them".

In the instant case, Applicant is claiming the broad genus of *Medicago sativa* alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest coupled with having 15% or greater more erect stems at late bloom when compared to specific commercial check varieties; however, the specification only provides details for how to produce a few alfalfa plants having the claimed characteristics, namely alfalfa varieties CW 75046 (see pages 25-29), CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45) and of the above mentioned varieties, only CW 75046, CW 83201, and CW 95026 are disclosed as having improved standability (i.e. more erect stems) and fast recovery after spring green-up or after harvest (see above cited pages). Alfalfa variety CW 85029 does not appear to have the claimed traits.

Applicant argues the specification provides sufficient direction and guidance as to how one skilled in the art could develop the alfalfa varieties of the present invention and that they have deposited representative alfalfa varieties which could be used by one

skilled in the art to develop additional varieties with the claimed traits using standard plant breeding protocols (see page 10, 3rd paragraph to page 11, lines 1-10 of 'Remarks' filed December 12, 2007).

This is not persuasive. The specification does not provide sufficient direction and guidance as to how one skilled in the art could develop the alfalfa varieties of the present invention because, for example, in the development of alfalfa variety 'CW 75046' the initial step discloses that 1,382 French lines (half-sib families or populations) were seeded into the field at West Salem, WI (see page 25, lines 15-16 of the specification); however, the specification does not provide any guidance regarding any of the 1,382 French lines.

This is important because Bouton (How alfalfa varieties are developed. *In* California/Nevada Alfalfa Symposium, 3-4 December, Reno, NV, 1998) teaches, "[collection and development of parents] is one of the most important decisions in the breeding program because the end product will only be as good as the parents which originally went into the process" (see pages 2-3). Thus, it is unclear how one skilled in the art would be able to use Applicant's specification to make and use the claimed invention when said invention is produced using uncharacterized material. This lack of guidance is also found in alfalfa variety 'CW 83201' (see page 29, line 14 to page 32, line 8), 'CW 85029' (see page 35, line 8 to page 37, line 22) and 'CW 95026' (see page 40, line 3 to page 42, line 20). The Examiner agrees that the deposited representative alfalfa varieties could be used by one skilled in the art to develop additional varieties with the claimed traits using standard plant breeding protocols; however, the claimed

invention is broadly drawn to any alfalfa plant having the claimed characteristics, even those that are made by other methods, or produced using different parental materials, than those described in the specification.

Applicant argues that a clear and detailed plant breeding roadmap to accomplishing the claimed invention has been provided and that the deposited varieties can be used to develop additional varieties with the claimed traits (see page 11, 1st full paragraph of 'Remarks' filed December 12, 2007).

This is not persuasive. The specification does not provide a clear and detailed plant breeding roadmap to accomplishing the claimed invention because the specification fails to provide any guidance regarding the parents used in the breeding methods to produce alfalfa varieties CW 75046, CW 83201, CW 85029 and CW 95026. It is unclear how one skilled in the art would be able to make and use the claimed invention using uncharacterized alfalfa lines as parental material. The Examiner agrees that the deposited representative alfalfa varieties could be used by one skilled in the art to develop additional varieties with the claimed traits using standard plant breeding protocols; however, the claimed invention is broadly drawn to any alfalfa plant having the claimed characteristics, even those that are made by other methods, or produced using different parental materials, than those described in the specification.

Claim Rejections - 35 USC § 102/103

Claims 2-4 and 6-19 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cluff et al (U.S. Patent

No. 6,143,951, November 7, 2000. The rejection is repeated for the reasons of record as set forth in the Office Action mailed June 12, 2007 (see pages 7-9). Applicant's arguments, filed December 12, 2007, have been fully considered but are not persuasive.

Applicant argues that the 'Reich Declaration' provides experimental data to definitively demonstrate that the cited reference is susceptible to lodging under sprinkler irrigation and thus cannot be prior art to the present invention (see page 12, 1st – 3rd paragraph of 'Remarks' filed December 12, 2007).

This is not persuasive. The cited reference teaches that 'WL-C290' has very fast recovery after harvest and excellent standability. Excellent standability is interpreted as high standability as defined on page 14, line 2 of the specification which is equivalent to more erect stem. Applicant's reference to the 'Reich Declaration' regarding lodging under sprinkler irrigation is not relevant because Applicant is arguing limitations, namely lodging under sprinkler irrigation, that are not in the claims.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 7:30 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson, Ph.D.
Examiner
Art Unit 1638
/David H Kruse/
Primary Examiner, Art Unit 1638
March 26, 2008